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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

WARE, DEBORAH K

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1651

32

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/028,514

Applicant(s)
Fike
Goffen et al.

Examiner
Deborah Ware

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1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 26, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-17, 20-24, 27-37, 73-77, 79-82, 106-109, 112, 140, and 1 is/are pending in the application.
- 4a) Of the above, claim(s) 79-82, 106-109, 112, 143-153, 155, and 156 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-17, 20-24, 27-37, 73-77, 140, 154, and 157-174 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 31 6) ☐ Other:

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Claims 1-3, 6-17, 20-24, 27-37, 73-77, 79-82, 106-109, 112, 140, 143-174 are pending.

The amendment and IDS filed November 26, 2002, have been received and entered. The references have been considered as indicated on the enclosed PTO-1449 Form. Extension of time of November 26, 2002, was granted and fee charged.

1. Claims 79-82, 106-109, 112, 143-153 and 155-156 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 27.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-3, 6-17, 20-24, 27-37, 73-77, 140, 154 and 157-174 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chessebeuf et al. (A) in view of Shuler et al. (B) and Parenteau et al.(C) all cited of record, see pages 4-5 of prior action.

Applicant's arguments filed November 26, 2002, have been fully considered but they are not persuasive. The two reasons provided at page 8 of Applicants' response are noted. The first reason is that one skilled in the art would not have been motivated to culture mammalian cells in suspension in media containing polyanionic or polycationic compound when the teachings of cited reference were considered in their entirety. However, the references have been applied in combination, and any deficiency of Chessebeuf is remedied by the application of Shuler which does teach use of sulfated polyanions for cell culture. Albeit the invention of Shuler is drawn to

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insect cells, the background of Shuler does teach that dextran sulfate has produced problems for animal cells and mammal cells. The teach of animal cells encompasses insect cells as well does animal cells encompass mammalian cells. Thus, the teachings of Shuler do indeed suggest that polyanionic compounds will provide successful results for the culturing of mammal cells, as claimed herein and taught by Chessebeuf et al. All that is needed in order to establish a prima facie case of obviousness is some suggestion to combine the teachings. The examiner thinks that this suggestion is provided by the cited prior art combination. With respect to Applicants other reason, the second reason referred to in their response, 293 cells as claimed herein, such cells would not have been expected to be cultured any differently from other animal cell lines disclosed in the art and based on knowledge generally available to one of ordinary skill in the art.

Also with respect to the replacement of protein in mammalian cell culture as claimed in claim 157 wherein Applicants set forth that this is not taught by the cited references. It should be noted that such chelator as zinc and iron are well known by those of skill in the art and protein is a well known contaminant of cell culture medium. Thus, to eliminate protein without a need for its presence in a cell culture medium and especially when its presence is well known to be undesirable it would have been obvious to those of skill in the art to eliminate protein from the mammalian cell culture medium.

Especially since the protein would serve no function to a method for culturing the cells in the cell culture medium from which the protein has been eliminated due to its undesirable effect and function. Therefore, the replacement of transferrin and insulin with chelator such as zinc and

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iron would have been expected to provide successful results. Parenteau does indeed teach chemically defined cell culture medium and methods for culturing mammal cells. Further, Parenteau does specifically teach replacing transferrin with iron chelator or ferrous ion chelator. Zinc is also a well known chelator and thus, to replace insulin with another chelator is at least suggested by Parenteau because they teach that other proteins such as transferrin can be replaced by chelator.

Therefore, the cited combination of references does indeed suggest the presently claimed replacements and thus, the limitations of the claims have been met by the cited prior art combination. Finally, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

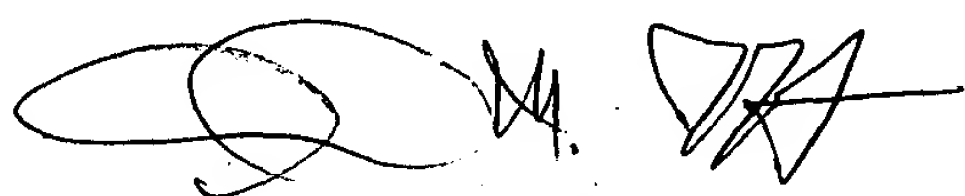
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Deborah K. Ware

February 22, 2003


DAVID M. NAFF
PRIMARY EXAMINER
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